

REMARKS**I. Continuity**

The Office stated that reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet. Applicants note that the insertion was requested in Paragraph 9 of the Rule 53 (b) continuation application, but applicants have amended the specification in order to comply. Additionally, the status of application 09/779,587 is abandoned.

II. Status of the claims

Claims 1-65 are pending in this action. Claims 2-23, 33-50, 52-22 and 59-65 have been withdrawn from consideration. Claims 1, 24-32, 51 and 56-58 have been rejected. In response to the Examiner's rejection, Claims 24, 25, and 51 have been amended. Claims 56-58 have been cancelled because they now claim the same subject matter as Claims 24-26 and therefore are redundant.

In the Office Action dated January 29, 2004, the Office objected to claims 24, 25, 51 and 56-58 for depending from non-elected inventions. Additionally claim 51 was objected to for reciting non-elected inventions (e.g., HCN2, HCN3, HCN4 and KAT1). Applicants have amended Claims 24, 25, and 51 to remove the language related to dependence on non-elected inventions. The Applicants have not further amended claim 51, however. Although HCN1 is the species currently under examination, if no prior art is cited against HCN1, the examination of the species is continued. MPEP § 809.02(c). The applicants would like to hold the amendment to Claim 51 in abeyance until it is clear how many species will be examined. The amendments that are made are fully supported by the specification as filed and to not constitute new matter. By this amendment, Applicants respectfully submit that they have placed all pending claims in condition for allowance.

III. Rejection under 35 U.S.C. § 112, first paragraph

The Office rejected claims 1, 24-32, 51 and 56-58 for failing to comply with the written description requirement of 35 U.S.C. 112, first paragraph. Applicants respectfully traverse.

The Office argues that the written description provided in the specification is insufficient to demonstrate possession of the claimed invention, since, according to the Office, the specification does not teach functional or structural characteristics of the polypeptide used in the claimed methods.

Office Action, page 4.

In the present application, Applicants claim a process for identifying substances that modulate the activity of hyperpolarization-activated cation channels. In an embodiment, the process comprises nucleic acids that code for the hyperpolarization-cation channel, such as HCN1.

Information which is well known in the art need not be described in detail in the specification.

MPEP § 2163(II)(A)(2). Here, the amino acid sequence of HCN1 is well known in the prior art.

See, e.g., B. Santoro et. al., *Cell* 93(5), 717-729 (1998); B. Santoro et. al., *Proc. Natl. Acad. Sci.*

U.S.A. 94(26), 14815-14820 (1997). Because a person skilled in the art would recognize that

Applicants had possession of the claimed HCN1 by reading the specification - the amino acid sequence of HCN1 was, afterall, known in the art - applicants respectfully submit that they meet the written description requirement without specifically reciting the amino acid sequence of HCN1.

Accordingly, Applicants respectfully request that the rejection be withdrawn.

IV. Rejection under 35 U.S.C. § 102

The Office rejected claim 1 under 35 U.S.C. §102(e) as being unpatentable over Krahn, et al. (U.S. Patent No. 6,420,183). Krahn teaches a process for the optical analysis of fluorescently labeled receptor/ligand interactions by masking the interfering background radiation through the introduction of a masking dye, which absorbs the excitation or emission light for the fluorescent dye. The Office argues that the limitations of Claim 1 of the instant Application are met since the claimed methods in Krahn can be used for detecting such changes in cell function. However, the process taught in Claim

1 comprises, among other things, the presence of an isoosmolar sodium-ion-free buffer, which maintains the hyperpolarization of the cation channel, making it possible to measure in a FLIPR the depolarization of the cell by a substance that can modulate the activity of the hyperpolarization-activated cation channel. Krahn does not teach the use of such a buffer. Additionally, the Office argues that Krahn discloses a method of detecting and quantifying changes in living cells using a FLIPR plate-reader. Krahn does *not* teach the use of FLIPR in the disclosed process. In fact, in the Background of the Invention, Krahn cites the use of FLIPR as a problem in the current state of the art that needs to be overcome - but provides no solution for overcoming it (*See Krahn*, Col. 1, lines 42-50). For these reasons, Krahn does not anticipate Claim 1. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 102(e) be withdrawn.

V. Rejection under 35 U.S.C. § 112, second paragraph

The Office has rejected claim 32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the inventions. Applicants respectfully traverse.

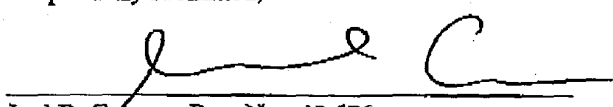
The Office argues that Claim 32 is rendered indefinite because of the phrase "high-throughput" since "high" is a conditional term and the Claim does not indicate in numerical terms the relative speed of the claimed process. *Office Action* at 6-7. However, the Office does state that the term is used extensively in the literature to describe a screening process that is significantly faster than conventional methods. *Id* at 6. "The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite . . . acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification." *See* MPEP § 2173.05(b). Under the Summary of the Invention, the specification basically states that high-throughput screening is used for the examination of the largest possible number of substances. Therefore, one of ordinary skill in the art would understand that a process which is a high-throughput process is one in which large numbers of chemical entities are

assessed for activity against a biological target. Additionally, the term is one that is known in the art. See, e.g., K. Rubenstein, Drug and Market Development (May 4, 2000) (cited at http://pharmalicensing.com/features/disp/957434612_39114af4b101b); D. Sands, EBR, Spring 2003 (cited at <http://www.samedanltd.com/members/archives/EBR/Spring2003/DavidSands.htm>.)

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 18-1982.

Respectfully submitted,


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